4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1120]

# Draft Guidance for Industry on Abbreviated New Drug Application Submissions--Refuse-to-Receive Standards; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "ANDA Submissions--Refuse-to-Receive Standards." This guidance is intended to assist applicants preparing to submit to FDA abbreviated new drug applications (ANDAs) and related submissions (i.e., prior approval supplements (PASs) for new strengths). The guidance contains details on what should be included in these submissions and highlights serious deficiencies that may cause FDA to refuse to receive the submission.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Johnny Young, Center for Drug Evaluation and Research (HFD-613), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8677.

SUPPLEMENTARY INFORMATION:

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled "ANDA Submissions--Refuse-to-Receive Standards." This guidance is intended to assist applicants preparing to submit to FDA ANDAs and PASs to ANDAs for which the applicant is seeking approval of a new strength of the drug product. The guidance contains details on what should be included in an ANDA and highlights serious deficiencies that may cause FDA to refuse to receive an ANDA. A refuse-to-receive decision indicates that FDA has determined that an ANDA is incomplete on its face, usually because of omissions.

With the enactment of the Generic Drug User Fee Act on July 9, 2012 (Public Law 112-144, Title III), FDA's Office of Generic Drugs (OGD) was tasked with a number of activities, including developing enhanced refusal to receive standards for ANDAs and related submissions. Recent data underscore the need for improvement in the quality of original ANDA submissions. Between 2009 and 2012, OGD refused to receive 497 ANDAs, primarily because the submissions contained serious deficiencies. FDA evaluates each incoming ANDA individually

to determine whether its format and content meet threshold criteria to permit a substantive review and can thus be received by FDA. The Agency cannot receive an ANDA unless it contains the information required under section 505(j) of the Federal Food, Drug, and Cosmetic Act and related regulations (e.g., 21 CFR 314.101(b)(1)). This guidance explains in some detail the kind of omissions that can lead to a refuse-to-receive determination. The guidance is intended to assist applicants preparing ANDAs and related submissions to help improve the quality of those submissions and ensure that their format and content meet the threshold criteria for FDA receipt and review.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on refusing to receive ANDAs and related submissions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information in 21 CFR part 314 for ANDA and related submissions has been approved under OMB control number 0910-0001.

## III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: September 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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